ANALYSIS

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Planned domiciliary versus hospital care for women with Preterm Prelabour Rupture of the Membranes (PPROM)

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ABSTRACT

Background: PPROM is encountered in 2.0% to 3.5% of pregnancies. Domiciliary care management is developing more and more in obstetrics for the psychological and financial burden of hospital care management to the patient but unfortunately, there were insufficient studies for reliable discharge criteria for the patient with PPROM. *Objective*: To compare efficacy & safety of planned domiciliary versus hospital care for women with PPROM on the fetal, neonatal, and maternal outcome. *Design*: The current study was conducted at Ain Shams University Maternity Hospital. A total of 4700 pregnant women were recruited from the outpatient clinic & emergency room and 3662 women were included in the study. *Patient and methods*: They were divided into two groups according to their preference; group (D) was counseled for domiciliary care, while group (H) was hospitalized. Take-home baby was assessed as a primary outcome and other maternal, fetal, and neonatal complications were recorded, moreover, latency period and mode of delivery were assessed. *Results:* When the two groups were compared, the number of take-home babies among the domiciliary group was 1726 (94.3%) while the number of take-home babies among the hospital group was 1681 (91.8%) representing that the number of take-home babies was significantly more frequent among the domiciliary group and there were also significant differences between the two groups as regard maternal and fetal outcomes in favor of the domiciliary management. *Conclusions*: We concluded that both types of care; domiciliary and hospital care can be applied safely after PPROM. The results of our study are assumed to have profound cost-saving effects in favor of domiciliary care, an important aspect regarding the ever-increasing health care costs and workloads.

Keywords: PPROM; Domiciliary care; Hospital care

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1. INTRODUCTION

The prevalence of prelabour rupture of the membranes (PPROM) at Ain Shams Maternity hospital ranged from 2.4% in 2011 to 4.7% in 2015 with the highest rate during 2013 (5.3%). The high rate of PPROM at Ain Shams Maternity hospital could be explained by the fact that it is a tertiary care level referral hospital. Only 4.3% of women presented with PPROM developed intra-amniotic infection. Regarding fetal outcome, 61.3% of infants developed a poor fetal outcome including; (fetal death and NICU admission), while 38.7% of infants had good fetal outcome (alive & well) (Abouseif et al., 2018). There is an international consensus that pregnancies affected by preterm prelabour rupture of the membranes (PPROM) represent a daily challenge for the obstetrician, and evidence-based guidelines should be available for the best management of such pregnancies. Evidence-based clinical practice guidelines represent a synthesis of literature and are designed to assist clinicians in making decisions regarding clinical practice (Tsakiridis et al., 2018).

Premature prelabour rupture of the membranes (PPROM) is the rupture of the fetal membranes before 37 weeks of gestation and before labor. The pathogenesis of spontaneous PROM is not well understood; possible risk factors include previous preterm labor, previous PPROM, cervical insufficiency, smoking, multiple gestation, and antepartum bleeding (Toukam et al., 2019). Maternal complications of PPROM include infection, sepsis, preterm labor, and placental abruption. Fetal complications of PPROM include preterm delivery, a non-reassuring fetal heart rate, umbilical cord prolapse and intrauterine fetal demise (Graham et al., 2019). PROM management has two main goals: reducing fetal immaturity at birth and avoiding intra-amniotic infection. Corticosteroid therapy has decreased morbidity in infants born 2–7 days after PPROM. Antenatal antibiotics can prolong the latency period between PPROM and birth by reducing the risk of neonatal infection. However, optimal timing for delivery remains a challenge and is controversial (Pasquier et al., 2019).

In 2014, a Cochrane meta-analysis included two articles that suggested that there were few differences in maternal & fetal complications between domiciliary & hospital management modalities. Domiciliary care is as suitable as conventional hospitalization for the management of PPROM as shown by recent studies. The main obstacle is the important heterogeneity of the eligibility criteria in those studies and there is currently no consensus as to this (Petit et al., 2018). The French recommendations evoke the possibility of domiciliary care management for selected women with PPROM, both the American College and the Royal College statements mention the lack of data to guide recommendations regarding hospital or outpatient care (Dussaux et al., 2018). When the term PROM study group compared outcomes of expectant management at home with expectant management in the hospital, women who were sent home were more likely to develop intra-amniotic infection. In multiple logistic regression analyses, women managed at home had a higher risk of infection in their newborns and nulliparamanaged at home were at increased risk of receiving antibiotics before delivery (Duff and Patrick, 2018).

2. PATIENTS AND METHODS

Type of Study

Cohort study

Study Setting

Ain Shams University Maternity Hospital

Study Period

From April 2019 to October2020

Study Population

The study included 3662 women with a history of preterm prelabour rupture of the membranes.

Inclusion Criteria

Maternal

- Women with PPROM ≥28 weeks and <37 weeks
- No signs of intra-amniotic infection
- Membranes rupture confirmed by a sterile speculum examination and decrease of amniotic fluid on ultrasound

Fetal

- Singleton, viable, cephalic-presenting fetus
- Morphologically-normal fetus by ultrasound

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- Reactive fetal heart rate tracing
- No evidence of meconium-stained liquor

Exclusion Criteria

- Query PPROM: A history of PPROM with no pooling of amniotic fluid from the cervix on a sterile speculum examination
- Maternal comorbidities: Hypertension, Diabetes mellitus, autoimmune disease, and other medical disorders in pregnancy.
- Patients with placenta previa
- Logistic problems interfering with follow-up:
  - Inability to check temperature every six hours, with parameters for notifying their clinician (temperature ≥38°C)
  - Non-Dependable transportation

Sample Size

Sample sizes of 1831 in each group achieve 80% power to detect a non-inferiority margin ratio in the group proportions of 1.5. The reference group proportion is 0.04. The treatment group proportion is assumed to be 0.06 under the null hypothesis of inferiority. The power was computed for the case when the actual treatment group proportion is 0.04. The one-sided Score test is the test statistic used is (Farrington & Manning). The significance level of the test is 0.050.

After enrolment, there were 2 equal groups:

- Group (D): Planned domiciliary care.
- Group (H): Planned hospital care.

Study Procedures

All women who met the inclusion criteria underwent full assessment:

Detailed History

History of demographic data (especially residency), medical co-morbidities, known hypersensitivities and the current condition (to exclude symptoms suggestive of intra-amniotic infection or preterm labour)

Physical Examination

General examination including: Pulse, blood pressure and temperature.

Abdominal examination: inspection for any scar, palpation of the abdomen for any tenderness & assessment of uterine contractions.

Sterile speculum examination: Confirm diagnosis by evident trickling of liquor & exclude any cervical changes.

Investigations

- Baseline hemoglobin, hematocrit, total leucocyte count and blood grouping
- Blood chemistry; AST, ALT and serum creatinine
- Viral markers; HBsAg, HCV Ab& HIV Ab
- Screening for Diabetes mellitus
- Urine analysis & urine C&S
- Antenatal scan: for assessment of liquor, number of feti, presentation, site of the placenta, fetal biometry & exclusion of congenital anomalies.
- Diagnostic test to confirm PPROM if pooling of amniotic fluid is not observed

Diagnosis of PPROM

In a woman presented with symptoms of PPROM, a speculum examination was offered to look for pooling of amniotic fluid:

If there was trickling of amniotic fluid, no diagnostic test was performed. If there was no trickling of amniotic fluid, the patient was excluded from our study (NICE 25 2015).

Study Interventions

Patients recruited in this study were divided into one of the following study groups according to their preferences for some ethical considerations & commenced antibiotic treatment according to the recent guidelines:

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Erythromycin 250 mg 4 times daily for 10 days following the diagnosis of PPROM, or until the women was established labour (whichever sooner) (GTG 99 2018).

Penicillin was used in patients who couldn't tolerate erythromycin (NICE 25 2015).

In cases of penicillin allergy: Cefazolin 1 g intravenously every 8 hours for 48 hours, followed by *cephalexin* 500 mg orally four times daily for five days. These drugs provide coverage for both GBS and Escherichia coli, the two major causes of neonatal infection(Duff and Patrick, 2018).

Group H (n= 1831)

Patients within this group were admitted at hospital for close monitoring of maternal & fetal well being & finally the neonatal outcome.

Group D (n= 1831)

Patients within this group were counseled for home care with self-monitoring for any symptoms suggestive of preterm labor, maternal or fetal distress.

Follow up

Hospital management plan

- Clinical evaluation of each patient by daily monitoring of baseline temperature, color & odor of liquor & uterine contractions
- Daily recording of fetal Movements
- Monitoring of the total leucocyte count once weekly
- Non-stress test once weekly
- Assessment of amniotic fluid index every 2 weeks
- Antenatal steroids after screening for diabetes mellitus: Dexamethasone 6 mg (intramuscular) every 12 hours for a total of 4 doses.

Domiciliary management plan

- Daily monitoring of baseline temperature, color & odor of liquor & uterine contractions (Labour pain)
- Daily recording of fetal quickening
- Antenatal steroids after screening for diabetes mellitus: Dexamethasone 6 mg (intramuscular) every 12 hours for a total of 4 doses (ACOG 171 2016).

Outpatient clinic follow-up

- Complete blood count once weekly for monitoring of the total leucocyte count
- Weekly non-stress test
- Follow up ultrasound every 2 weeks for assessment amniotic fluid index
- Women were hospitalized if there was evidence of labour or, intra-amniotic infection or non-reassuring fetal movements.
- An emergency contact phone number was available for all cases for communication in emergency situation & their contact numbers were available with the investigator for proper follow up.

Statistical analysis

The collected data was coded, tabulated, and statistically analyzed using IBM SPSS statistics (Statistical Package for Social Sciences) software version 22.0, IBM Corporation, Chicago, USA, 2013. Descriptive statistics was done for quantitative data as minimum & maximum of the range as well as mean±SD (standard deviation) for quantitative normally distributed data, while it was done for qualitative data as number and percentage.

Inferential analyses were done for quantitative variables using Shapiro-Wilk test for normality testing, independent t-test in cases of two independent groups with normally distributed data. In qualitative data, inferential analyses for independent variables was done using Chi square test for differences between proportions. The significance level was at 5%. When P value is <0.050 is significant, otherwise is non-significant.

Intervention values were calculated as follows

- Rate elevation=Study Rate – Control Rate.
- Efficacy= (Study Rate – Control Rate) / Study rate

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- Relative Rate= Study Rate / Control Rate
- Number needed to treat = 1 / (Study Rate – Control Rate)

Intention to treat analysis

If women in the domiciliary group were admitted at hospital for any obstetric indication (Threatened preterm labor, abruptio-placentae, decreased fetal movements…) the data will be analyzed based on their treatment allocation according to intention to treat basis.

3. RESULTS

Participant time-line

Participant time-line are mentioned in chart 1.

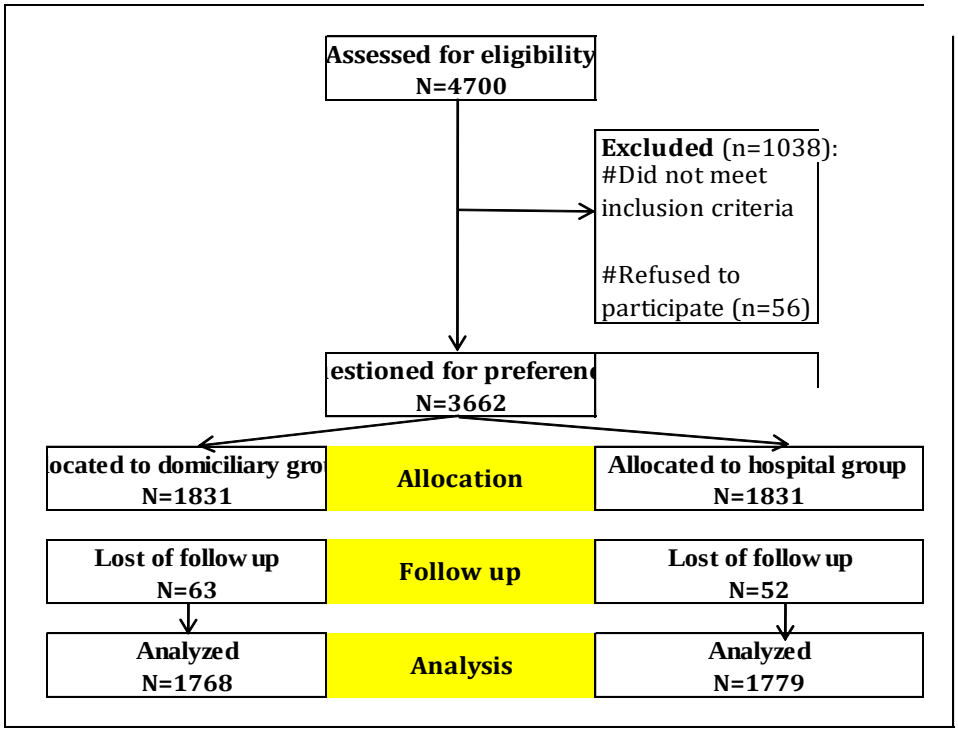

Chart 1 Participant time-line

Demographic characteristics

No significant difference between the studied groups regarding demographic characteristics as shown in Table 1.

Table 1 demographic characteristics

Items	Measure	Domiciliary (N=1831)	Hospital (N=1831)	P-value
Age (years)	Mean±SD	32.6±4.4	32.4±4.4	^0.437
	Range	18.0–45.0	18.0–45.0	
BMI (kg/m^2)	Mean±SD	29.2±1.9	29.1±1.9	^0.180
	Range	22.2–36.2	22.6–35.9	
Parity	Primi	654 (35.7%)	680 (37.1%)	#0.372
	Multi	1177 (64.3%)	1151 (62.9%)	

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GA (weeks)	Mean±SD	32.1±1.7	32.2±1.7	^0.267
	Range	28.0–36.0	28.0–36.0	

^Independent t-test. #Chi square test

Gestational age at delivery

Table (2) shows that: Gestational age at delivery was significantly higher in domiciliary group than in hospital group.

Table 2 Gestational age at delivery

Measures	Domiciliary (N=1831)	Hospital (N=1831)	^P-value
Mean±SD	34.3±1.9	34.0±1.9	<0.001*
Range	28.0–37.0	28.0–37.0	
Mode	35.0	34.0	
Median (1st–3rd IQ)	34.0 (33.0–36.0)	34.0 (33.0–35.0)	
Domiciliary care versus hospital care			
Items		hMean±SE	95% CI
Duration difference		0.3±0.1	0.2–0.4

IQ: Interquartukes. ^Independent t-test #Paired t-test.CI: Confidence interval, *Significant

Gestational age prolongation

Table 3 shows that Gestational age prolongation was significantly higher in domiciliary group than in hospital group.

Table 3 Gestational age prolongation

Measures	Domiciliary (N=1768)	Hospital (N=1779)	^P-value
Mean±SD	18.3±7.6	15.8±6.6	<0.001*
Range	2.0–40.0	1.0–39.0	
Domiciliary care versus hospital care			
Items	Mean±SE	95% CI	
Duration difference	2.5±0.2	2.0–3.0	

^Independent t-test #Paired t-test.CI: Confidence interval, *Significant

Cesarean section

Table 4 shows that Cesarean section was significantly less frequent in domiciliary group than in hospital group.

Table 4 Cesarean section

Outcome	Domiciliary (N=1831)	Hospital (N=1831)	#P-value
CS	141 (7.7%)	356 (19.4%)	<0.001*
VD	1690 (92.3%)	1475 (80.6%)	
Domiciliary care versus hospital care			
Items		Value	95% CI
Rate elevation		11.7%	9.6%–13.7%
Efficacy		14.6%	11.8%–17.3%
Relative Rate		0.87	0.85–0.89
Number needed to prevent		8.52	7.28–10.42

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#Chi square test. *Significant, CI: Confidence interval

Intra-amniotic infection

Table 5 shows that Intra-amniotic infection was significantly less frequent in domiciliary group than in hospital group.

Table 5 Intra-amniotic infection

Outcome	Domiciliary (N=1831)	Hospital (N=1831)	#P-value
Positive	357 (19.5%)	614 (33.5%)	<0.001*
Negative	1474 (80.5%)	1217 (66.5%)	
Domiciliary care versus hospital care			
Items		Value	95% CI
Rate elevation		14.0%	11.2%–16.8%
Efficacy		21.1%	16.5%–25.9%
Relative Rate		0.83	0.79–0.86
Number needed to prevent		7.13	5.94–8.95

#Chi square test. *Significant, CI: Confidence interval

Neonatal weight

Table 6 shows that Neonatal weight was significantly higher in domiciliary group than in hospital group.

Table 6 shows that: Neonatal weight

Measures	Domiciliary (N=1768)	Hospital (N=1779)	^P-value
Mean±SD	2283±201	2104±200	<0.001*
Range	1649–2883	1218–2736	
Domiciliary care versus hospital care			
Items	Mean±SE	95% CI	
Weight difference	179±7	165–192	

^Independent t-test #Paired t-test.CI: Confidence interval, *Significant

Table 7 shows that According to linear regression for factors affecting birth weight; domiciliary care was a determinant factor for birth weight regardless the gestational age at delivery.

Table 7 linear regression for factors affecting birth weight

Factors	B	SE	P-value	95% CI
Domiciliary care	0.014	0.004	0.002*	0.005–0.022
GA at delivery (week)	0.142	0.001	<0.001*	0.141–0.143
Constant	-0.451	0.009	<0.001*	-0.470–-0.433

β: Regression coefficient, SE: Standard error, CI: Confidence interval, *significant,

Neonatal infection

Table 8 shows that Neonatal infection was significantly less frequent in domiciliary group than in hospital group.

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Table 8 Neonatal infection

Outcome	Domiciliary (N=1831)	Hospital (N=1831)	#P-value
Positive	210 (11.5%)	371 (20.3%)	<0.001*
Negative	1621 (88.5%)	1460 (79.7%)	
Domiciliary care versus hospital care			
Items		Value	95% CI
Rate elevation		8.8%	6.4%–11.1%
Efficacy		11.0%	7.9%–14.1%
Relative Rate		0.90	0.88–0.93
Number needed to prevent		11.37	9.02–15.59

#Chi square test. *Significant, CI: Confidence interval

Respiratory distress syndrome

Table 9 shows that Respiratory distress syndrome was significantly less frequent in domiciliary group than in hospital group.

Table 9 Respiratory distress syndrome

Outcome	Domiciliary (N=1831)	Hospital (N=1831)	#P-value
Positive	79 (4.3%)	163 (8.9%)	<0.001*
Negative	1752 (95.7%)	1668 (91.1%)	
Domiciliary care versus hospital care			
Items		Value	95% CI
Rate elevation		4.6%	3.0%–6.1%
Efficacy		5.0%	3.2%–6.7%
Relative Rate		0.95	0.94–0.97
Number needed to prevent		21.80	16.44–33.76

#Chi square test. *Significant, CI: Confidence interval

NICU admission

Table 10 shows that Neonatal observation room referral was significantly less frequent in domiciliary group than in hospital group. Table 11 shows that NICU admission was significantly less frequent in domiciliary group than in hospital group.

Table 10 Neonatal observation room

Outcome	Domiciliary (N=1831)	Hospital (N=1831)	#P-value
Positive	453 (24.7%)	573 (31.3%)	<0.001*
Negative	1378 (75.3%)	1258 (68.7%)	
Domiciliary care versus hospital care			
Items		Value	95% CI
Rate reduction		6.6%	3.6%–9.5%

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Efficacy	26.5%	13.7%–40.8%
Relative Rate	0.79	0.71–0.88
Number needed to prevent	15.26	10.54–27.82

#Chi square test. *Significant, CI: Confidence interval

Table 11 NICU admission

Outcome	Domiciliary (N=453)	Hospital (N=573)	§P-value
Admission	81 (17.9%)	159 (27.7%)	<0.001*
Checkup	372 (82.1%)	414 (72.3%)	
Domiciliary care versus hospital care			
Items		Value	95% CI
Rate reduction		9.9%	4.5%–14.9%
Efficacy		55.2%	21.6%–99.0%
Relative Rate		0.64	0.50–0.82
Number needed to prevent		10.13	6.71–22.15

§Fisher's Exact test. *Significant, CI: Confidence interval

Perinatal mortality

Table 12 shows that perinatal mortality was significantly less frequent in domiciliary group than in hospital group. Table 13 shows that According to logistic regression for factors affecting Perinatal mortality; hospital care did not add any benefit in preventing perinatal mortality rate.

Table 12 Perinatal mortality

Outcome	Domiciliary (N=1831)	Hospital (N=1831)	#P-value
Positive	42 (2.3%)	98 (5.4%)	<0.001*
Negative	1789 (97.7%)	1733 (94.6%)	
Domiciliary care versus hospital care			
Items		Value	95% CI
Rate reduction		3.1%	1.8%–4.2%
Efficacy		133.3%	61.4%–238.8%
Relative Rate		0.43	0.30–0.62
Number needed to prevent		32.70	24.03–55.71

#Chi square test. *Significant, CI: Confidence interval

Table 13 logistic regression for factors affecting Perinatal mortality

Factors	β	SE	P-value	OR (95% CI)
Domiciliary care	-0.378	0.212	0.075	0.685 (0.453–1.038)
GA at delivery (week)	-0.043	0.013	0.001*	0.958 (0.934–0.982)

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Constant	-1.816	0.442	<0.001*

β: Regression coefficient, SE: Standard error, OR: Odds ratio, CI: Confidence interval, *significant

Take-home baby

Table 14 shows that Take-home baby was significantly more frequent in domiciliary group than in hospital group.

Table 14 Take-home baby

Outcome	Domiciliary (N=1831)	Hospital (N=1831)	#P-value
Positive	1726 (94.3%)	1681 (91.8%)	0.003*
Negative	105 (5.7%)	150 (8.2%)	
Domiciliary care versus hospital care			
Items		Value	95% CI
Rate elevation		2.5%	0.8%–4.1%
Efficacy		2.6%	0.8%–4.3%
Relative Rate		1.03	1.01–1.04
Number needed to treat		40.7	24.4–132.2

#Chi square test. *Significant, CI: Confidence interval

4. DISCUSSION

About 2.0% to 3.5% of pregnancies are complicated by PPROM, and the optimal management for patients with this condition is not clear. Given the paucity of data supporting the safety of domiciliary management, the clinical practice guidelines from the American College of Obstetricians and Gynecologists recommend inpatient management from the time of rupture of membranes until delivery (ACOG, 2013). A Cochrane review to assess the safety, cost and women's views about planned domiciliary versus hospital care for women with PPROM identified only two relatively small trials (116 women) so that significant differences between the groups could not be detected. Retrospective cohort studies from Canada (173 women), and France (414 women), found no difference in maternal morbidity, or neonatal morbidity or mortality between the groups (Atrolia et al., 2020). Even though hospital care is prudent, it poses significant difficulty for the patient with a high-risk pregnancy removed from her family and home environment. In addition to this, the logistics of providing inpatient care for patients who remain clinically well for weeks at a time are challenging from a resource management perspective (Catt et al., 2016).

Many women had reported lower self-esteem, greater anxiety and depression and less optimal family functioning in previous quantitative studies on hospitalization during high risk pregnancy. Experienced fear, anxiety for the unknown and perceived immobility and inactivity are amongst stressors and emotions during hospitalization (Kent et al., 2015). E-Health developed due to recent technological advances was defined as health services and information delivered or enhanced through the Internet and related technologies. Increased patient engagement and satisfaction with better access to health care and the possibility to reduce clinic costs with equal or better health outcomes were the potential positive effects of the use of e-Health. E-Health has already found its way in perinatal care and its implementation is likely to disperse globally in the next decade (Van den Heuvel et al., 2018).

Our study was a prospective cohort study comparing hospital versus domiciliary management in women, who came to Ain Shams Maternity Hospital, as regard efficacy & safety of planned domiciliary versus hospital care for women with preterm prelabour rupture of the membranes (PPROM) on fetal, neonatal and maternal outcome. A total number of 4700 pregnant women were enrolled in this study and assessed for eligibility. Only 3662 pregnant women had met inclusion criteria while 1038 were excluded as there were 982 women didn't meet inclusion criteria & 56 pregnant women refused to participate. Then they were divided into 2 groups according to their preference. Patients' preference was incorporated to ensure that care was provided based on the individual patient's perspective, preferences, and needs. The findings of this study provided some suggestions for implementation from the patient perspective including the demand for patient education, a clear antenatal management plan, adequate participant selection for domiciliary care and weekly hospital visits.

The core of our study was to clarify the safety & efficacy of the domiciliary management as an alternative option for management of PPROM targeting population preferring hospital care to decrease burden at our tertiary care hospital for low risk

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patients. Also, most of literature stated that prolonged hospitalization has financial, as well as non-financial costs to the family unit in term of isolation and psychological stress. For domiciliary group, 1831 women were allocated for this study but only 1768 women were analyzed as 63 women had lost follow up. The allocated patients were discharged to home after initial assessment and they were instructed to come back if: any abnormal color of liquor, rising of temperature, decreased fetal kicks, bleeding or uterine contractions. For hospital group, 1831 women were allocated for this study but only 1779 women were analyzed as 52 women had lost follow up. The allocated patients had expectant management till labor pains began. There were no significant differences between the studied groups regarding demographic characteristics for age, BMI parity and gestational age at admission taking into consideration that the choice of gestational age threshold was based on the literature and also based on the limit of management in our hospital.

Regarding the selection criteria, Petit et al. (2018) stated that there were three criteria that significantly increased the risk of severe complications: PPROM occurring before 26 weeks (P = 0.008), non-cephalic fetal presentation (P = 0.02), and oligohydramnios (P = 0.02). The risk was increased when any of the three criteria were associated with PPROM, (1 criterion, odds ratio [OR] 1.6; 2 criteria, OR 6.9 and 3 criteria, OR 32.8). Another study showed that, the threshold of 28 weeks in conventional hospitalization, and showed that the rate of severe complications was 64.0% before 28 weeks, as opposed to 11.0% after this time, and another study found that, before 28 weeks, the rate of severe complications was 83.3% and 50.9% in both groups of study.

In our study the gestational age at delivery was higher in women discharged to home with the mean of 34.3±1.9 (weeks) as compared to women admitted at hospital with the mean of 34.0±1.9 (weeks) (P< 0.001) with statistically significant difference between the 2 groups according to gestational age at delivery & as regard gestational age prolongation; it was significantly higher in domiciliary group than in hospital group with mean duration difference 2.5±0.2 (days). And about birth before 37 weeks' gestation, it was significantly less frequent in domiciliary group than in hospital group to be 85.5% of women versus 90.3% respectively. Our results coincides with a previous study of 395 women whom were included after PPROM, 191 were managed as outpatients and 204 in hospital. In the domiciliary group the length of latency period was longer than in the hospital group (39.0 [20, 66] versus 21.0 [13, 42]) days; p<0.001) (Guckert et al., 2019).

Another study showed that women receiving hospital care had delivered at an earlier gestational age, a median of 11 days earlier than those managed as outpatients. This may reflect that clinicians considered these women to be at higher risk of earlier delivery. It is also possible that hospital care increases the likelihood of earlier delivery, for instance by increasing the risk of nosocomial infections (Gonsález et al., 2019). There are several hypotheses to explain this latency period difference. First, inpatient care may increase the likelihood of earlier delivery by increasing the risk of nosocomial infections. We noticed that there was less intra-amniotic infection in the domiciliary group versus the hospital group. Second, the stressors associated with prolonged antenatal hospitalization may have an important psychological impact and we can hypothesize that domiciliary care reduced this stress. Patients get a better comfort and quality of life which increased indirectly the latency. Third, hospitalization may be iatrogenic for women managed long-term, and as more interventions occur (i.e., vaginal examination), then biological sampling leading to antibiotic therapy and probably more induced birth. About the mode of delivery, we found that cesarean section was significantly less frequent in the domiciliary group than in the hospital group with a total number of 141 (7.7%) cesarean deliveries among the domiciliary group versus 356 (19.4%) cesarean deliveries among the hospital group.

This was what also found by Cochrane systematic review El Senoun et al. (2014) that delivery by cesarean section was more frequent in women managed by hospital care (RR (random effects) 0.28, 95% CI 0.07 to 1.15). Other study found that women were more likely to have cesarean section if they were cared for at domiciliary rather than in hospital (13.0% vs. 8.9%; P #.007) (EL Senoun et al., 2014). Hannah et al. (2000), found that women managed at home compared with in a hospital, had a higher risk of cesareans (OR 1.48 95% CI 1.03, 2.14, P =.04). The current study showed that intra-amniotic infection was significantly less frequent in the domiciliary group than in the hospital group as there were 357 women representing 19.5% of the domiciliary group had developed intra-amniotic infection versus 614 women representing 33.5% of the hospital group had developed intra-amniotic infection. This corresponds to the result of a study by Catt et al. (2016) in which the placenta pathology showed evidence of chorioamnionitis in 64% of inpatients and 47% of outpatients. This may represent a baseline difference between the two groups in favor of the outpatient group.

There is a secondary analysis of women who were expectantly managed at home in the TERM-PROM study indicated that women managed at home were more satisfied with their care, but they experienced higher rates of maternal infection (10.1% vs. 6.4%; P #.006) (Hannah et al., 2000). But another RCT (2002) compared expectant management at home (n=29) with expectant management in hospital (n=27) for women with term PROM. There was no differences were found between 2 groups for maternal infection 14/24 versus 11/23, $\chi 2 = 0.521$ P = 0.47 (Jomeen et al., 2002). About El Senoun et al. (2014) also found that there was no evidence of differences between groups for intra-amniotic infection. And this finding correlated with other studies in which clinical

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intra-amniotic infection was observed in 30 (15.7%) in domiciliary group versus 49 (24.0%) in hospital group (p=0.039) (Guckert et al., 2020). There was significant difference in the neonatal weight between the 2 groups in our study to be significantly higher in the domiciliary one with a mean difference of 179±7 (gm) as the mean of birth weight were 2283±201 & 2104±200 grams in the domiciliary & the hospital group respectively.

When birth weight was adjusted for confounders we found that that domiciliary care had significant increasing effect on birth weight reflecting that not only the prolonged latency period but also the domiciliary care has an implication for the birth weight in favor to the outpatient group and this may be hypothesized to the psychological impact, intimate family care and the nutritional status of the domiciliary group. These results correspond to a study by Bouchghoul et al. (2019) in which the median birth weight was also lower for neonates in the inpatient group: 1,632 g versus 1,790 g in the outpatient group (p = 0.04). Another study by Dussaux et al. (2018) referred that birth weight was significantly higher in the domiciliary group where the mean birth weight was 1971.8 ± 531.2 grams in contrast to the hospital group where the mean birth weight was 1676.7 ± 536.5 grams. While in Carlan 1993 study, there was no significant difference as regard birth weight between the two study groups.

Regarding NICU admission among the studied groups, there were 453 neonates were referred to the neonatal observation room representing 24.7% of the domiciliary group and there were only 81 neonates (17.9%) admitted & 372 were discharged after check-up after exclusion of neonatal sepsis & respiratory distress according the standard hospital protocols while there were 573 neonates were referred to neonatal observation room representing 31.3% of the hospital group and there were only 159 neonates (27.7%) admitted so NICU admission was significantly less frequent in domiciliary group. About NICU duration, it was lower in the domiciliary group with the mean of 7.7±3.8 (days) as compared to the hospital group with the mean of 9.9±3.5 (days) (P < 0.001) with statistically significant difference between the 2 groups according to NICU duration. Concerning the neonatal complications in the current study we noticed that most of these complications including neonatal sepsis, respiratory distress syndrome, Necrotising enterocolitis, neonatal encephalopathy & postural deformities were non significantly less frequent in domiciliary group than in hospital group.

In a similar study by Guckert et al. (2020) concerning neonatal outcome, there were less transfer in neonatal intensive care, less respiratory distress syndrome in the outpatient group than in the hospital group (29.4% versus 47.5% ; p< 0.001), less neonatal sepsis (13.9% versus 22.1% ; p < 0.037), less chronic neonatal lung disease (20.2% versus 36.3% ; p ¼0.001), less bronchodysplasia (2.7% versus 9.8%; p¼0.004) and less pulmonary arterial hypertension (4.8% versus 10.3% ; p¼0.04). There were also less neonatal death in the outpatient group (2.1% versus 3.9%) but the difference was not statistically significant. Also Dussaux et al. (2018) noticed that babies of women who received outpatient care had a higher birth weight, required less admission to NICU and spent fewer days in NICU in case of admission.

In our study, the perinatal mortality was significantly different among the studied groups with a total number of 42 cases (2.3%) among the domiciliary group versus 98 cases (5.4%) among the hospital group. Also, the Stillbirth was significantly less frequent in domiciliary group than in hospital group where there were 6 cases (0.3%) of stillbirths in the domiciliary group while there were just 18 cases (1.0%) of stillbirths in the hospital group. But as regard Neonatal mortality, the total number of neonatal deaths among the domiciliary group was 36 (2.0%) while the total number of neonatal deaths among the hospital group was 80 (4.4%) indicating that neonatal mortality was significantly less frequent in domiciliary group than in hospital group. According to the confounding factors affecting perinatal mortality, only gestational age at delivery had significant decreasing effect on Perinatal mortality but there was no difference between hospital care and domiciliary care in the composite outcome measure of perinatal mortality. This agrees with the results of a study by Beckmann et al. (2013) for IUFD, in which the rate of stillbirth among the hospitalized women was significantly higher When adjusted for confounders, there was no difference regarding the outcome of perinatal morbidity and mortality between hospital care and outpatient care (AOR 1.37; 95%CI 0.55–3.47).

In contrast to a study by Catt et al. (2016) which stated that there was no significant difference in rates of stillbirth and neonatal mortality between the two groups to be 4 (3%) in the outpatient group versus 5 (4%) in the inpatient group (p > 0.999). Another study of neonatal outcome of PPROM among hospital & domiciliary group had observed severe complications in the 2 groups: 2 IUFD in the outpatient group against 0 in the inpatient group and 4 neonatal deaths versus 8. The low rate of stillbirth in that study didn't not allow the authors to make conclusion. Even if some authors discourage homecare management in PPROM to prevent those complications, they believed that the events occurred at home would have taken place even in hospital with the same issue. Moreover, perinatal mortality (IUFD and neonatal death) had the same rate in the two groups. Finally; according to our study, the number of take-home babies among the domiciliary group was 1726 (94.3%) while the number of take-home babies among the hospital group was 1681 (91.8%) representing that the number of take-home babies was significantly more frequent in domiciliary group than in hospital group.

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There were no comparable results in all previous studies regarding take-home babies & our study was the first up to date study referring to that outcome which was the primary outcome of our study reflecting the aim & target of our study to find that domiciliary care wasn't inferior to hospital care in the women suffering from PPROM concerning maternal, fetal & neonatal outcome.

5. CONCLUSION

This study adds to the current knowledge on women's perspectives on antenatal monitoring from home during low-risk pregnancy as social changes are demanding a shift to home-based patient-centered care, and domiciliary care provides flexibility to both physicians and patients decreasing the demand for more hospital personnel or clinic space with the same safety & efficacy as hospital care management. As regard maternal outcomes, we found that latency period was significantly longer in the domiciliary group with less frequent cesarean rate with less risk of intra-amniotic infection and shorter antenatal and postnatal hospital stay. Concerning fetal and neonatal outcomes, we found that neonatal birth weight was significantly higher in the domiciliary group with less NICU admission and less neonatal complications including RDS. By the end of this study we found that there was a higher rate of take-home babies in the domiciliary group with less perinatal mortality ensuring the success of the outpatient care as a substitute for the standard hospital care.

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Author Contributions

The study was designed by Shereif Mohammed Abd El Hameed; Ahmed S. Farag; Mohamed Hamed Abd El-Aziz Salama; Ahmed M. Selim. data collection, analyzed and manuscript preparation by Ahmed M Selim, data interpretation and manuscript reviewed by Shereif Mohammed Abd El Hameed; Ahmed S. Farag; Mohamed Hamed Abd El-Aziz Salama

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Conflict of Interest

The authors declare that there are no conflicts of interests.

Informed consent

Written & Oral informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this manuscript.

Ethical approval

The study was approved by the Medical Ethics Committee of Obstetrics and Gynaecology Department at Ain Shams University, to ensure following the standard ethical principles governing research involving human subjects. These data was registered on clinical trials with the following ID: NCT04413019.

Data and materials availability

All data associated with this study are present in the paper.

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